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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FLICK, JASON E	

ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
09/20/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,966	SOHN, ZE'EV	
	Examiner	Art Unit	
	JASON FLICK	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-91 and 93-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-91 and 93-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Examiner acknowledges the reply filed on 07/13/2010 in which no claims were amended. Claims 1-85, 92, and 99-124 have been cancelled. Currently, claims 86-91 and 93-98 are pending for examination in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 93-98 are rejected under 35 U.S.C. 102(e) as being anticipated by Coston et al. (PGPub 2002/0010414).

4. [Claims 93 and 94] Coston teaches an apparatus for facilitating transport of a substance through an area of skin of a subject (figure 4, item 400), the area defining a set of ablation sites (figure 4, item 50), the apparatus comprising: a plurality of electrodes, which are adapted to be placed in contact with the area of the skin at the ablation sites (figure 4, item 16); a control unit (figure 4, item 12), adapted to drive, during successive first, second, and third time periods, a current capable of ablating stratum corneum of the skin to a first one, a second one, and a third one of the

electrodes, the first one of the electrodes being non-adjacent to the second one of the electrodes, and the second one of the electrodes being non-adjacent to the third one of the electrodes, so as to facilitate transdermal transport of the substance (page 7, paragraphs [0068]-[0069]; page 13, paragraph [0122]); wherein the control unit is adapted to drive the current in sequence to typically maximize a minimum distance between electrodes into which current is driven during successive time periods (page 13, paragraph [0122]) and is adapted to drive the current such that a sum of distances between temporally adjacent ones of the electrodes into which current is driven is typically greater than such sum would be if a sequence of electrodes is generated randomly (page 13, paragraph [0122]).

5. [Claims 95-98] Coston teaches the limitations of claim 94, upon which claims 95-98 depend. Coston teaches the apparatus as claimed, wherein the control unit is capable of controlling the waveform, frequency, voltage, amperage, and duration of the current (page 7, paragraphs [0068]-[0069]); therefore the apparatus taught by Coston is capable of driving current during 10 successive time periods. Also, Coston discloses that the device is capable of being configured such that a distance between successive sites of application of the current during each of the periods is greater than 3 mm (page 13, paragraph [0122]). In addition, Coston teaches the control unit is capable of being adapted to drive the current during at least 10 successive time periods into respective ones of the electrodes, such that, for each of the periods, during temporally adjacent ones of the time periods, the current is driven into non- adjacent electrodes; or such that

during none of the time periods is the current driven into adjacent electrodes (page 13, paragraph [0122]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 86-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coston et al. (PGPub 2002/0010414), in view of Eggers et al. (USPN 6,024,733).

9. [Claims 86 and 87] Coston teaches an apparatus and method for facilitating transport of a substance through an area of skin of a subject (figure 4, item 400), the area defining a set of ablation sites (figure 4, item 50), the apparatus comprising: a plurality of electrodes, which are adapted to be placed in contact with the area of the skin at the ablation sites (figure 4, item 16); a method comprising driving current in a sequence into more than one of the ablation sites (figure 4); and a control unit (figure 4,

item 12), adapted to drive, during successive first, second, and third time periods, a current capable of ablating stratum corneum of the skin to a first one, a second one, and a third one of the electrodes, the first one of the electrodes being non- adjacent to the second one of the electrodes, and the second one of the electrodes being non-adjacent to the third one of the electrodes, so as to facilitate transdermal transport of the substance (page 7, paragraphs [0068]-[0069]; page 13, paragraph [0122]). Coston does not specifically disclose a method wherein driving the current in the sequence comprises configuring the sequence to generally maximize a minimum distance between ablation sites, wherein a sum of distances between temporally adjacent ablation sites into which current is driven is typically greater than such sum would be if the sequence is generated randomly. However, Eggers teaches a system and method of tissue ablation which discloses a method comprising driving the current in sequence to typically maximize a minimum distance between electrodes into which current is driven during successive time periods, such that a sum of distances between temporally adjacent ones of the electrodes into which current is driven is typically greater than such sum would be if a sequence of electrodes is generated randomly (column 15, lines 26-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method taught by Coston with the method of maximizing the minimum distances between temporally adjacent ablation sites, as taught by Eggers, in order to minimize patient discomfort and/or prevent concentrated areas of tissue ablation.

10. [Claims 88 and 89] Coston and Eggers teach the method steps of claim 87, upon which claims 88 and 89 depend. Coston teaches the method as claimed, wherein the control unit is capable of controlling the waveform, frequency, voltage, amperage, and duration of the current (page 7, paragraphs [0068]-[0069]). Coston and Eggers do not specifically state the current is driven 10 successive times or that the distance between successive sites of application of the current during each of the periods is greater than 3mm. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to drive the current a select number of times or set a particular minimum distance between successive applications, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

11. [Claims 90 and 91] Coston and Eggers teach the method steps of claim 87, upon which claims 90 and 91 depend. Coston teaches the method as claimed, wherein the control unit is capable of controlling the waveform, frequency, voltage, amperage, and duration of the current (page 7, paragraphs [0068]-[0069]). Coston and Eggers do not specifically state the current is driven 10 successive times. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to drive the current a select number of times, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In addition, Eggers teaches the method, such that, for each of the periods, during temporally adjacent ones of the time periods, the

current is driven into non- adjacent electrodes; or such that during none of the time periods is the current driven into adjacent electrodes (column 15, lines 26-39).

Response to Arguments

12. Applicant's arguments filed 07/13/2010 have been fully considered but they are not persuasive. Applicant's representative asserts that the prior art of record does not disclose the invention as claimed.

13. Examiner has fully considered the applicant's arguments but they are not persuasive. It is the examiner's position that given a careful reading, the claims do not distinguish over the prior art of record.

14. Applicant's representative argues that the prior art to Coston does not teach the limitations of claims 93-98. The examiner respectfully disagrees. Specifically, applicant's representative asserts Coston does not teach an apparatus "**adapted to** maximize a minimum distance between ablation sites into which current is driven during successive time periods" or "**adapted to** drive the current such that a sum of distances between temporally adjacent ones of the electrodes into which current is driven is typically greater than such sum would be if a sequence of the electrodes in generated randomly." Although applicant's representative correctly states that apparatus claims may define an invention in terms of functional language, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural

limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971). As cited in the rejection above, Coston clearly teaches a system meeting all structural limitations which is capable of meeting the disclosed functional limitations (page 13, paragraph [0122]).

15. Applicant's representative argues that the prior art to Coston, in view of Eggers, does not teach the limitations of claims 86-91. The examiner respectfully disagrees. Specifically, applicant's representative asserts the combination of Coston and Eggers does not disclose a method comprising driving current in sequence such that a minimum distance is maximized between ablation sites during successive time periods, such that a sum of distances is typically greater than such sum would be if a sequence of electrodes is generated randomly. The examiner respectfully disagrees. At cited in

the rejection above, Eggers clearly discloses these limitations: "By **sequentially** energizing **one or several** electrodes, the interaction between adjacent electrodes can be minimized (for the case of energizing several electrode positioned at the maximum possible spacing within the overall envelope of the electrode array) or eliminated (for the case of energizing only a single electrode at any one time)." Based on the Eggers reference, the examiner fails to see how applicant's representative can conclude that Eggers only teaches maximizing the minimum distance between electrodes when electrodes are simultaneously energized. Eggers clearly states the electrodes are energized **sequentially**.

16. Furthermore, applicant's claim language utilizes terms such as "generally" and "typically" to describe the functional limitations of the driving current. The use of this language implies such functionality does not necessarily occur in all instances. Given the broadest reasonable interpretation, driving current in sequences not conforming to the functional language would still fall within the scope of the claim limitations.

17. Therefore, the examiner asserts the prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./
Examiner, Art Unit 3763
09/16/2010

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763